Commercial/Healthcare Exchange PA Criteria

Effective: November 2016

Prior Authorization: Soliqua

Products Affected: Soliqua ***(***insulin glargine and lixisenatide) 100/33: Insulin glargine 100 units and lixisenatide 33 mcg per mL Subcutaneous Solution Pen-injector

Medication Description: Insulin glargine; lixisenatide is a subcutaneous injection containing a combination of basal insulin (insulin glargine) and a glucagon-like peptide-1 receptor agonist (GLP-1 RA) (lixisenatide). The combination is used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM). The combination of allows for administration once-daily at the same time each day given within the hour before the first meal of the day. Insulin glargine gives a flat and stable effect on blood glucose throughout the day; lixisenatide stimulates insulin secretion and lowers inappropriately high glucagon secretion in a glucose-dependent manner.

Covered Uses: Soliqua 100/33 is a combination of insulin glargine and lixisenatide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Exclusion Criteria:

1. Hypoglycemia
2. Patients with a history of pancreatitis
3. Patients with a history of gastroparesis
4. Treatment of patients with type 1 diabetes mellitus
5. Treatment of patients with diabetic ketoacidosis

Required Medical Information:

1. Diagnosis
2. Past medications tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an endocrinologist, or a physician who focuses in the treatment of diabetes and/or disorders of the endocrine system

Coverage Duration: 12 months

Other Criteria: *Approve if the patient has met all of the following criteria:*

A. The patient has a diagnosis of type 2 diabetes mellitus; AND
B. The patient's A1C is > 7%; AND
C. The patient will not be using Soliqua in combination with any other product containing a GLP-1 receptor agonist; AND
D. The patient has documented trial, failure or contraindication to Xultophy

References:

1. Product Information: SOLIQUA(R) 100/33 subcutaneous injection, insulin glargine lixisenatide subcutaneous injection. sanofi-aventis US LLC (per FDA), Bridgewater, NJ, 2019.

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/2016
2	Update	Adopted EH Template; Added Rybelsus as preferred GLP1; Added criteria: The patient will not be using Soliqua in combination with any other product containing a GLP-1 receptor agonist; added exclusions to match FDA label Removed criteria requiring trials of meds other than Xultophy	All	11/22/2019